

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)


Total Number of Pages in This Submission

Application Number	10/713,472
Filing Date	November 14, 2003
First Named Inventor	Charles A. Vacanti
Art Unit	1615
Examiner Name	Not yet assigned
Attorney Docket Number	VAC 102 CON (2)

ENCLOSURES (Check all that apply)

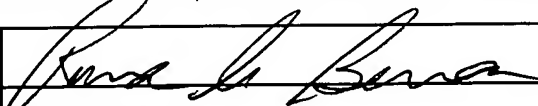
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): seven (7) pages of PTO-1449; return postcard
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Pabst Patent Group LLP		
Signature			
Printed name	Tiffany B. Salmon		
Date	December 7, 2004	Reg. No.	55,589

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Ronna Berman	Date	December 7, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

The PTO did not receive the following
 listed items(s) FORs and NPLs

VAC 102 CON (2) / 095150-00007

63 10 2003

PTO/SB/17 (10-04)

Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0.00

Complete if Known

Application Number 10/713,472
Filing Date November 14, 2003
First Named Inventor Charles A. Vacanti
Examiner Name Not yet assigned
Art Unit 1615
Attorney Docket No. VAC 102 CON (2)

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number
Deposit Account Name

50-3129

Pabst Patent Group LLP

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 790	2001 395	Utility filing fee	
1002 350	2002 175	Design filing fee	
1003 550	2003 275	Plant filing fee	
1004 790	2004 395	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
23	-23 = 0	X	
3	-3** = 0	X	
Multiple Dependent			

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 88	2201 44	Independent claims in excess of 3
1203 300	2203 150	Multiple dependent claim, if not paid
1204 88	2204 44	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 430	2252 215	Extension for reply within second month	
1253 980	2253 490	Extension for reply within third month	
1254 1,530	2254 765	Extension for reply within fourth month	
1255 2,080	2255 1,040	Extension for reply within fifth month	
1401 340	2401 170	Notice of Appeal	
1402 340	2402 170	Filing a brief in support of an appeal	
1403 300	2403 150	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,370	2501 685	Utility issue fee (or reissue)	
1502 490	2502 245	Design issue fee	
1503 660	2503 330	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 790	2809 395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 790	2810 395	For each additional invention to be examined (37 CFR 1.129(b))	
1801 790	2801 395	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 0.00

SUBMITTED BY

Name (Print/Type) Tiffany B. Salmon

Registration No. (Attorney/Agent) 55,589

(Complete if applicable)

Telephone (404) 879-2153

Signature

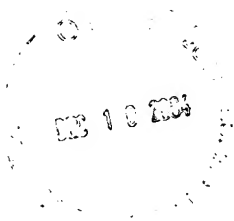
Date December 1, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

VAC 102 CON (2) / 095150-00007



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Charles A. Vacanti, Joseph P. Vacanti, and Martin P. Vacanti

Serial No.: 10/713,472

Art Unit: 1615

Filed: November 14, 2003

Examiner: Not Yet Assigned

For: *GUIDED DEVELOPMENT AND SUPPORT OF HYDROGEL-CELL
COMPOSITIONS*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including 7 pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/658,912, filed September 11, 2000, now abandoned, which is a continuation of Application Serial No. 09/200,033, filed November 25, 1998, which issued as U.S. Patent 6,171,610 on January 9, 2001, which is a continuation-in-part of U.S. Serial No. 09/066,038, filed April 24, 1998, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission.

However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-3129.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,191,747	03-1980	Scheicher	
4,846,835	07-1989	Grande	
4,997,443	03-1991	Walthall et al.	
5,041,138	08-1991	Vacanti et al.	
5,071,644	12-1991	Viegas et al.	
5,082,670	01-1992	Gage et al.	
5,126,141	06-1992	Henry	
5,192,326	03-1993	Bao et al.	
5,277,911	01-1994	Viegas et al.	
5,292,516	03-1994	Viegas et al.	
5,294,446	03-1994	Schlameus et al.	
5,298,260	03-1994	Viegas et al.	
5,300,295	04-1994	Viegas et al.	
5,306,501	04-1994	Viegas et al.	
5,318,780	06-1994	Viegas et al.	
5,405,366	04-1995	Scheicher	
5,410,016	04-1995	Hubbell et al.	
5,411,883	05-1995	Boss et al.	
5,443,950	08-1995	Naughton et al.	
5,512,600	04-1996	Mikos et al.	
5,514,378	05-1996	Mikos et al.	
5,529,914	06-1996	Hubbell et al.	
5,567,612	10-1996	Vacanti et al.	
5,575,815	11-1996	Slepian et al.	
5,578,485	11-1996	Naughton et al.	
5,589,376	12-1996	Anderson et al.	
5,593,974	01-1997	Rosenberg et al.	
5,667,778	09-1997	Atala	
5,696,175	12-1997	Mikos et al.	
5,709,854	01-1998	Griffith-Cima et al.	
5,716,404	02-1998	Vacanti et al.	
5,736,372	04-1998	Vacanti et al.	
5,750,376	05-1998	Weiss et al.	
5,753,506	05-1998	Johe	
5,759,830	06-1998	Vacanti et al.	
5,762,926	06-1998	Gage et al.	

5,770,193	06-1998	Vacanti et al.
5,770,417	06-1998	Vacanti et al.
5,786,216	07-1998	Dionne et al.
5,795,790	08-1998	Schinstine et al.
5,804,178	09-1998	Vacanti et al.
5,824,489	10-1998	Anderson et al.
5,827,735	10-1998	Young et al.
5,830,651	11-1998	Cauley et al.
5,834,029	11-1998	Bellamkonda et al.
5,851,832	12-1998	Weiss et al.
5,855,610	01-1999	Vacanti et al.
6,027,744	02-2000	Vacanti et al.

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
0 361 957	04-04-1990	Organogenesis, Inc.	EP
WO 92/06702	04-30-1992	New York University	PCT
WO 93/16687	02-09-1993	Board of Regents, The University of Texas System	PCT
WO 93/24627	12-09-1993	Case Western Reserve University, The Metrohealth System, and The University of Akron	PCT
WO 94/25079	11-10-1994	Massachusetts Institute of Technology and Children's Medical Center Corporation	PCT
WO 94/25080	11-10-1994	Massachusetts Institute of Technology and Children's Medical Center Corporation	PCT
WO 96/15226	05-1996	Neurospheres Holding Ltd.	PCT
WO 96/40304	12-19-1996	Reprogenesis, Inc.	PCT
WO 98/30678	07-16-1998	Laywell, et al.	PCT

Publications

AHMED, et al., "BDNF enhances the differentiation but not the survival of CNS stem cell-derived neuronal properties" *The Journal of Neuroscience* 15(8): 5765-5778 (1995).

BOUWENS and BLAY, "Islet morphogenesis and stem cell markers in rat pancreas" *The Journal of Histochemistry and Cytochemistry* 44(9): 947-951 (1996).

CORNELIUS, et al., "In vitro-generation of islets in long-term cultures of pluripotent stem cells from adult mouse pancreas" *Horm. Metab. Res.* 29(6); 271-277 (1997).

CRAIG et al., "In Vivo Growth Factor Expansion of Endogenous Subependymal Neural Precursor Cell Populations in the Adult Mouse Brain," *The Journal of Neuroscience*, 16:2649-2658, Apr. 15, 1996.

DABEVA, et al., "Differentiation of pancreatic epithelial progenitor cells into hepatocytes following transplantation into rat liver" *PNAS* 94: 7356-7361 (1997).

DAVIS et al., "A Self-Renewing Multipotential Stem Cell in Embryonic Rat Cerebral Cortex," *Nature*, 372:263-269, Nov. 17, 1994.

EMURA, "Stem cells of the respiratory epithelium and their *in vitro* cultivation" *In Vitro Cell Dev. Biol. Anim.* 33(1): 3-14 (1997).

FREDERIKSEN et al., "Proliferation and Differentiation of Rat Neuroepithelial Precursor Cells In Vivo," *The Journal of Neuroscience*, 8:1144-1151, Apr. 1988.

FERRINGA et al., "Regeneration of Corticospinal Axons in the Rat," *Annals of Neurology*, 2:315-321, Oct. 1977.

GAGE et al., "Survival and Differentiation of Adult Neuronal Progenitor Cells Transplanted to the Adult Brain," *Proc. Natl. Acad. Sci. USA*, 92:11879-11883, Dec. 1995.

GRITTI, et al., "Multipotent stem cells from the adult mouse brain proliferate and self-renew in response to basic fibroblast growth factor" *The Journal of Neuroscience* 16(3): 1091-1100 (1996).

HOULE et al., "Bridging a Complete Transection Lesion of Adult Rat Spinal Cord with Growth Factor-Treated Nitrocellulose Implants," *Journal of Neural Transplantation & Plasticity*, 5:115-124, 1994.

JOHANSSON, et al., "Identification of a neural stem cell in the adult mammalian central nervous system" *Cell* 96: 25-34 (1999).

KANDEL, et al., "Chapter 49: The autonomic nervous system and the hypothalamus" in Principles of Neural Science, 4th Edition, McGraw-Hill Publishing, New York, New York.

LACHYANKAR et al., "Embryonic Precursor Cells that Express Trk Receptors: Induction of Different Cell Fates by NGF, BDNF, NT-3, and CNTF," *Experimental Neurology*, 144:350-360, 1997.

MEHLER, et al., "Cytokines regulate the cellular phenotype of developing neural lineage species" *Int. J. Devl. Neuroscience* 13(3/4): 213-240 (1995).

MORSHEAD et al., "Neural Stem Cells in the Adult Mammalian Forebrain: A Relatively Quiescent Subpopulation of Subependymal Cells," *Neuron*, 13:1071-1082, Nov. 1994.

MURPHY, et al., "Neural stem cells" *Journal of Investigative Dermatology Symposium Proceedings* 2(1); 8-13 (1997).

NOTTER, et al., "Neuronal properties of monkey adrenal medulla *in vitro*" *Cell Tissue Research* 244: 69-76 (1986).

PALMER and GAGE, "FGF-2 responsive neuronal progenitors reside in proliferative and quiescent regions of the adult rodent brain" *Molecular and Cellular Neuroscience* 6: 474-486 (1995).

PALMER and GAGE, "The adult rat hippocampus contains primordial neural stem cells" *Molecular and Cellular Neuroscience* 8: 389-404 (1997).

RAY et al., "Proliferation, Differentiation, and Long-Term Culture of Primary Hippocampal Neurons," *Proc. Natl. Acad. Sci. USA*, 90:3602-3606, Apr. 1993.

RAY et al., "Spinal Cord Neuroblasts Proliferate in Response to Basic Fibroblast Growth Factor," *The Journal of Neuroscience*, 14:3548-3564, Jun. 1994.

REYNOLDS et al., "Clonal and Population Analyses Demonstrate that an EGF-Responsive Mammalian Embryonic CNS Precursor is a Stem Cell," *Developmental Biology*, 175:1-13, 1996.

REYNOLDS et al., "Generation of Neurons and Astrocytes from Isolated Cells of the Adult Mammalian Central Nervous System," *Science*, 255:1707-1710, Mar. 27, 1992.

REYNOLDS et al., "A Multipotent EGF-Responsive Striatal Embryonic Progenitor Cell Produces Neurons and Astrocytes," *The Journal of Neuroscience*, 12:4565-4574, Nov. 1992.

ROSKAMS, et al., "Undifferentiated progenitor cells in focal nodular hyperplasia of the liver" *Histopathology* 28(4): 291-299 (1996).

SANTA-OLALLA and COVARRUBIAS, "Epidermal growth factor (EGF), transforming growth factor- α (TGF- α), and basic fibroblast growth factor (bFGF) differentially influence neural precursor cells fo mouse embryonic mesencephalon" *Journal of Neuroscience Research* 42: 172-183 (1995).

SEIDL and UNSICKER, "Survival and neuritic growth of sympathoadrenal (chromaffin) precursor cells *in vitro*" *Int. J. Dev. Neuroscience* 7(5): 465-473 (1989).

SHIHABUDDIN et al., "The Adult CNS Retains the Potential to Direct Region-Specific Differentiation of a Transplanted Neuronal Precursor Cell Line," *The Journal of Neuroscience*, 15:6666-6678, Oct. 1995.

SHIHABUDDIN et al., "FGF-2 is Sufficient to Isolate Progenitors Found in the Adult Mammalian Spinal Cord," *Experimental Neurology*, 148:577-586, 1997.

SHIHABUDDIN et al., "Induction of Mature Neuronal Properties in Immortalized Precursor Cells Following Grafting into the Neonatal CNS," *Journal of Neurocytology*, 25:101-111, 1996.

STANTON et al., "The Growth of Chondrocytes Using Gelfoam.RTM. as a Biodegradable Scaffold," *Journal of Materials Science: Materials in Medicine* 6, 739-744, 1996.

SUHONEN et al., "Differentiation of Adult Hippocampus-Derived Progenitors into Olfactory Neurons *in Vivo*," *Nature*, 383:624-627, Oct. 17, 1996.

TAUPIN and GAGE, "Adult neurogenesis and neural stem cells of the central nervous system in mammals" *Journal of Neuroscience Research* 69(6): 745-749 (2002).

TAYLOR et al., "Widespread Engraftment of Neural Progenitor and Stem-Like Cells Throughout the Mouse Brain," *Transplantation Proceedings*, 29:845-847, 1997.

WAREJCKA, et al., "A population of cells isolated from rat heart capable of differentiating into several mesodermal phenotypes" *Journal of Surgical Research* 62(2): 233-242 (1996).


WEISS et al., "Multipotent CNS Stem Cells are Present in the Adult Mammalian Spinal Cord and Ventricular Neuroaxis," *The Journal of Neuroscience*, 16:7599-7609, Dec. 1, 1996.

ZULEWSKI, et al., "Multipotential nestin-positive stem cells isolated from adult pancreatic islets differentiate *ex vivo* into pancreatic endocrine, exocrine, and hepatic phenotypes" *Diabetes* 50(3): 521-533 (2001).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,


Tiffany B. Salmon
Reg. No. 55,589

Dated: December 7, 2004

PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2153 (Telephone)
(404) 879-2160 (Fax)



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/713,472
		Filing Date	November 14, 2003
		First Named Inventor	Charles A. Vacanti
		Group Art Unit	1615
		Examiner Name	
Sheet 1 of 7	Attorney Docket Number	VAC 102 CON (2)	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,191,747		Scheicher	03-1980	
		4,846,835		Grande	07-1989	
		4,997,443		Walthall et al.	03-1991	
		5,041,138		Vacanti et al.	08-1991	
		5,071,644		Viegas et al.	12-1991	
		5,082,670		Gage et al.	01-1992	
		5,126,141		Henry	06-1992	
		5,192,326		Bao et al.	03-1993	
		5,277,911		Viegas et al.	01-1994	
		5,292,516		Viegas et al.	03-1994	
		5,294,446		Schlameus et al.	03-1994	
		5,298,260		Viegas et al.	03-1994	
		5,300,295		Viegas et al.	04-1994	
		5,306,501		Viegas et al.	04-1994	
		5,318,780		Viegas et al.	06-1994	
		5,405,366		Scheicher	04-1995	
		5,410,016		Hubbell et al.	04-1995	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0 361 957		Organogenesis, Inc.	04-04-1990		
		PCT	WO 92/06702		New York University	04-30-1992		
		PCT	WO 93/16687		Board of Regents, The University of Texas System	02-09-1993		

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/713,472		
		Filing Date	November 14, 2003		
		First Named Inventor	Charles A. Vacanti		
		Group Art Unit	1615		
		Examiner Name			
Sheet	2	of	7	Attorney Docket Number	VAC 102 CON (2)

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,411,883		Boss et al.	05-1995	
		5,443,950		Naughton et al.	08-1995	
		5,512,600		Mikos et al.	04-1996	
		5,514,378		Mikos et al.	05-1996	
		5,529,914		Hubbell et al.	06-1996	
		5,567,612		Vacanti et al.	10-1996	
		5,575,815		Slepian et al.	11-1996	
		5,578,485		Naughton et al.	11-1996	
		5,589,376		Anderson et al.	12-1996	
		5,593,974		Rosenberg et al.	01-1997	
		5,667,778		Atala	09-1997	
		5,696,175		Mikos et al.	12-1997	
		5,709,854		Griffith-Cima et al.	01-1998	
		5,716,404		Vacanti et al.	02-1998	
		5,736,372		Vacanti et al.	04-1998	
		5,750,376		Weiss et al.	05-1998	
		5,753,506		Johe	05-1998	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 93/24627		Case Western Reserve The Metrohealth System, and The University of Akron	12-09-1993		
		PCT	WO 94/25079		Massachusetts Institute of Technology, and Children's Medical Center Corporation	11-10-1994		
Examiner's Signature _____ Date Considered _____								

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/713,472		
		Filing Date	November 14, 2003		
		First Named Inventor	Charles A. Vacanti		
		Group Art Unit	1615		
		Examiner Name			
Sheet	3	of	7	Attorney Docket Number	VAC 102 CON (2)

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,759,830		Vacanti et al.	06-1998	
		5,762,926		Gage et al.	06-1998	
		5,770,193		Vacanti et al.	06-1998	
		5,770,417		Vacanti et al.	06-1998	
		5,786,216		Dionne et al.	07-1998	
		5,795,790		Schinstine et al.	08-1998	
		5,804,178		Vacanti et al.	09-1998	
		5,824,489		Anderson et al.	10-1998	
		5,827,735		Young et al.	10-1998	
		5,830,651		Cauley et al.	11-1998	
		5,834,029		Bellamkonda et al.	11-1998	
		5,851,832		Weiss et al.	12-1998	
		5,855,610		Vacanti et al.	01-1999	
		6,027,744		Vacanti et al.	02-2000	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁸
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 94/25079		Massachusetts Institute of Technology, and Children's Medical Center Corporation	11-10-1994		
		PCT	WO 94/25080		Massachusetts Institute of Technology, and Children's Medical Center Corporation	11-10-1994		
		PCT	WO 96/15226		Neurospheres Holding Ltd.	05-1996		
		PCT	WO 96/40304		Reprogenesis, Inc.	12-19-1996		
		PCT	WO 98/30678		Laywell, et al.	07-16-1998		

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/713,472		
		Filing Date	November 14, 2003		
		First Named Inventor	Charles A. Vacanti		
		Group Art Unit	1615		
		Examiner Name			
Sheet	4	of	7	Attorney Docket Number	VAC 102 CON (2)

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		AHMED, et al., "BDNF enhances the differentiation but not the survival of CNS stem cell-derived neuronal properties" <i>The Journal of Neuroscience</i> 15(8): 5765-5778 (1995).	
		BOUWENS and BLAY, "Islet morphogenesis and stem cell markers in rat pancreas" <i>The Journal of Histochemistry and Cytochemistry</i> 44(9): 947-951 (1996).	
		CORNELIUS, et al., "In vitro-generation of islets in long-term cultures of pluripotent stem cells from adult mouse pancreas" <i>Horm. Metab. Res.</i> 29(6): 271-277 (1997).	
		CRAIG et al., "In Vivo Growth Factor Expansion of Endogenous Subependymal Neural Precursor Cell Populations in the Adult Mouse Brain," <i>The Journal of Neuroscience</i> , 16:2649-2658, Apr. 15, 1996.	
		DABEVA, et al., "Differentiation of pancreatic epithelial progenitor cells into hepatocytes following transplantation into rat liver" <i>PNAS</i> 94: 7356-7361 (1997).	
		DAVIS et al., "A Self-Renewing Multipotential Stem Cell in Embryonic Rat Cerebral Cortex," <i>Nature</i> , 372:263-269, Nov. 17, 1994.	
		EMURA, "Stem cells of the respiratory epithelium and their <i>in vitro</i> cultivation" <i>In Vitro Cell Dev. Biol. Anim.</i> 33(1): 3-14 (1997).	
		FREDERIKSEN et al., "Proliferation and Differentiation of Rat Neuroepithelial Precursor Cells In Vivo," <i>The Journal of Neuroscience</i> , 8:1144-1151, Apr. 1988.	
		FERRINGA et al., "Regeneration of Corticospinal Axons in the Rat," <i>Annals of Neurology</i> , 2:315-321, Oct. 1977.	
		GAGE et al., "Survival and Differentiation of Adult Neuronal Progenitor Cells Transplanted to the Adult Brain," <i>Proc. Natl. Acad. Sci. USA</i> , 92:11879-11883, Dec. 1995.	
		GRITTI, et al., "Multipotent stem cells from the adult mouse brain proliferate and self-renew in response to basic fibroblast growth factor" <i>The Journal of Neuroscience</i> 16(3): 1091-1100 (1996).	
		HOULE et al., "Bridging a Complete Transection Lesion of Adult Rat Spinal Cord with Growth Factor-Treated Nitrocellulose Implants," <i>Journal of Neural Transplantation & Plasticity</i> , 5:115-124, 1994.	
Examiner's Signature			Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/713,472		
		Filing Date	November 14, 2003		
		First Named Inventor	Charles A. Vacanti		
		Group Art Unit	1615		
		Examiner Name			
Sheet	5	of	7	Attorney Docket Number	VAC 102 CON (2)

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		JOHANSSON, et al., "Identification of a neural stem cell in the adult mammalian central nervous system" <i>Cell</i> 96: 25-34 (1999).	
		KANDEL, et al., "Chapter 49: The autonomic nervous system and the hypothalamus" in <u>Principles of Neural Science</u> , 4 th Edition, McGraw-Hill Publishing, New York, New York.	
		LACHYANKAR et al., "Embryonic Precursor Cells that Express Trk Receptors: Induction of Different Cell Fates by NGF, BDNF, NT-3, and CNTF," <i>Experimental Neurology</i> , 144:350-360, 1997.	
		MEHLER, et al., "Cytokines regulate the cellular phenotype of developing neural lineage species" <i>Int. J. Devl. Neuroscience</i> 13(3/4): 213-240 (1995).	
		MORSHEAD et al., "Neural Stem Cells in the Adult Mammalian Forebrain: A Relatively Quiescent Subpopulation of Subependymal Cells," <i>Neuron</i> , 13:1071-1082, Nov. 1994.	
		MURPHY, et al., "Neural stem cells" <i>Journal of Investigative Dermatology Symposium Proceedings</i> 2(1); 8-13 (1997).	
		NOTTER, et al., "Neuronal properties of monkey adrenal medulla <i>in vitro</i> " <i>Cell Tissue Research</i> 244: 69-76 (1986).	
		PALMER and GAGE, "FGF-2 responsive neuronal progenitors reside in proliferative and quiescent regions of the adult rodent brain" <i>Molecular and Cellular Neuroscience</i> 6: 474-486 (1995).	
		PALMER and GAGE, "The adult rat hippocampus contains primordial neural stem cells" <i>Molecular and Cellular Neuroscience</i> 8: 389-404 (1997).	
		RAY et al., "Proliferation, Differentiation, and Long-Term Culture of Primary Hippocampal Neurons," <i>Proc. Natl. Acad. Sci. USA</i> , 90:3602-3606, Apr. 1993.	
		RAY et al., "Spinal Cord Neuroblasts Proliferate in Response to Basic Fibroblast Growth Factor," <i>The Journal of Neuroscience</i> , 14:3548-3564, Jun. 1994.	
		REYNOLDS et al., "Clonal and Population Analyses Demonstrate that an EGF-Responsive Mammalian Embryonic CNS Precursor is a Stem Cell," <i>Developmental Biology</i> , 175:1-13, 1996.	
Examiner's Signature			Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/713,472		
		Filing Date	November 14, 2003		
		First Named Inventor	Charles A. Vacanti		
		Group Art Unit	1615		
		Examiner Name			
Sheet	6	of	7	Attorney Docket Number	VAC 102 CON (2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		REYNOLDS et al., "Generation of Neurons and Astrocytes from Isolated Cells of the Adult Mammalian Central Nervous System," <i>Science</i> , 255:1707-1710, Mar. 27, 1992.	
		REYNOLDS et al., "A Multipotent EGF-Responsive Striatal Embryonic Progenitor Cell Produces Neurons and Astrocytes," <i>The Journal of Neuroscience</i> , 12:4565-4574, Nov. 1992.	
		ROSKAMS, et al., "Undifferentiated progenitor cells in focal nodular hyperplasia of the liver" <i>Histopathology</i> 28(4): 291-299 (1996).	
		SANTA-OLALLA and COVARRUBIAS, "Epidermal growth factor (EGF), transforming growth factor- α (TGF- α), and basic fibroblast growth factor (bFGF) differentially influence neural precursor cells from mouse embryonic mesencephalon" <i>Journal of Neuroscience Research</i> 42: 172-183 (1995).	
		SEIDL and UNSICKER, "Survival and neuritic growth of sympathoadrenal (chromaffin) precursor cells <i>in vitro</i> " <i>Int. J. Dev. Neuroscience</i> 7(5): 465-473 (1989).	
		SHIHABUDDIN et al., "The Adult CNS Retains the Potential to Direct Region-Specific Differentiation of a Transplanted Neuronal Precursor Cell Line," <i>The Journal of Neuroscience</i> , 15:6666-6678, Oct. 1995.	
		SHIHABUDDIN et al., "FGF-2 is Sufficient to Isolate Progenitors Found in the Adult Mammalian Spinal Cord," <i>Experimental Neurology</i> , 148:577-586, 1997.	
		SHIHABUDDIN et al., "Induction of Mature Neuronal Properties in Immortalized Precursor Cells Following Grafting into the Neonatal CNS," <i>Journal of Neurocytology</i> , 25:101-111, 1996.	
		STANTON et al., "The Growth of Chondrocytes Using Gelfoam.RTM. as a Biodegradable Scaffold," <i>Journal of Materials Science: Materials in Medicine</i> 6, 739-744, 1996.	
		SUHONEN et al., "Differentiation of Adult Hippocampus-Derived Progenitors into Olfactory Neurons <i>in Vivo</i> ," <i>Nature</i> , 383:624-627, Oct. 17, 1996.	
		TAUPIN and GAGE, "Adult neurogenesis and neural stem cells of the central nervous system in mammals" <i>Journal of Neuroscience Research</i> 69(6): 745-749 (2002).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Please type a plus sign (+) inside this box →



+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>		Complete if Known			
		Application Number	10/713,472		
		Filing Date	November 14, 2003		
		First Named Inventor	Charles A. Vacanti		
		Group Art Unit	1615		
		Examiner Name			
Sheet	7	of	7	Attorney Docket Number	VAC 102 CON (2)

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		TAYLOR et al., "Widespread Engraftment of Neural Progenitor and Stem-Like Cells Throughout the Mouse Brain," Transplantation Proceedings, 29:845-847, 1997.	
		WAREJCKA, et al., "A population of cells isolated from rat heart capable of differentiating into several mesodermal phenotypes" <i>Journal of Surgical Research</i> 62(2): 233-242 (1996).	
		WEISS et al., "Multipotent CNS Stem Cells are Present in the Adult Mammalian Spinal Cord and Ventricular Neuroaxis," <i>The Journal of Neuroscience</i> , 16:7599-7609, Dec. 1, 1996.	
		ZULEWSKI, et al., "Multipotential nestin-positive stem cells isolated from adult pancreatic islets differentiate <i>ex vivo</i> into pancreatic endocrine, exocrine, and hepatic phenotypes" <i>Diabetes</i> 50(3): 521-533 (2001).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.

+